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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,379	08/15/2001	Christian Kropf	H 3763 PCT/U	8884

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EXAMINER
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GRAFFEO, MICHELLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/868,379

Applicant(s)

KROPF ET AL.

Examiner

Michelle Graffeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/19/2005
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on July 19, 2005 has been entered.

The IDS filed July 19, 2005 has been entered and considered (see attached).

Claims 8-14 are pending and examined. Prior indications of allowable subject matter are withdrawn in view of the below indicated rejections.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by S. Zhang and K.E. Gonsalves, *J.Mater.Sci.Mater, Med.* 8 (1997) 25. Regarding claim 8, Zhang *et al.* teach a solution (see Experimental procedures) comprising rod-like shaped hydroxyapatite particles having a length of 25 nm (see page 26 second col), wherein the hydroxyapatite crystallizes into hexagonal rhombic prisms (see Introduction) and polyacrylic acid (see page 25 Experimental Procedures section which recites "the starting precipitates without polyacrylic acid were prepared in a similar way" which teaches that the method described includes salt precipitates with polyacrylic acid. See also Figure 1, which is a micrograph of rod-like hydroxyapatite crystals with polyacrylic acid in the system) to which the calcium is bonded (see page 28). Regarding claim 11, Zhang *et al.* also teach a method of making rod-like shaped hydroxyapatite particles comprising a 30ml solution in which 7.63g of calcium nitrite was dissolved and 2 g of polyacrylic acid (2g of polyacrylic acid is at least .01% of the solution) was added (see Experimental procedures) such that the precipitated hydroxyapatite products were de-agglomerated as shown in Figure 1.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over S. Zhang and K.E. Gonsalves, J.Mater.Sci.Mater, Med. 8 (1997) 25. in view of PCT/IB97/01634 to Rudin *et al.*

Regarding claim 8, Zhang *et al.* teach a solution (see Experimental procedures) comprising rod-like shaped hydroxyapatite particles having a length of 25 nm (see page 26 second col), wherein the hydroxyapatite crystallizes into hexagonal rhombic prisms (see Introduction) and polyacrylic acid (see page 25 Experimental Procedures section which recites "the starting precipitates without polyacrylic acid were prepared in a similar way" which teaches that the method described includes salt precipitates with polyacrylic acid. See also Figure 1, which is a micrograph of rod-like hydroxyapatite crystals with polyacrylic acid in the system) to which the calcium is bonded (see page 28). Regarding claim 11, Zhang *et al.* also teach a method of making rod-like

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shaped hydroxyapatite particles comprising a 30ml solution in which 7.63g of calcium nitrite was dissolved and 2 g of polyacrylic acid (2g of polyacrylic acid is at least .01% of the solution and not greater than 10% absent evidence to the contrary) was added (see Experimental procedures) such that the precipitated hydroxyapatite products were de-agglomerated as shown in Figure 1.

Zhang *et al.* do not teach a solution in which the hydroxyapatite is present in an amount of from 1 to 40% or a toothpaste comprising same.

Rudin *et al.* teach (claim 13) a rod-like nanoparticulate (60nm L X 15 nm W X 5 nm T; see page 2, 5<sup>th</sup> paragraph) composition for stomatological indications with a water content of 32.2% (see page 6 Example 1) which can be used as a paste or gel to cure microdefects and stimulate reparative osteogenesis (claim 14-see page 3 paragraph 4) comprising humectants and binders (see page 3 last paragraph) wherein the hydroxyapatite can be present in an amount of 0.2 or 2% (see Examples 1 and 2 on page 6) or generally in an amount of from .1 to 50% (claims 9,10 - see page 3 paragraph 4).

Zhang *et al.* do not teach a process of preparing a suspension comprising a calcium salt and a phosphate salt with a pH below 3 and precipitating the product by increasing the pH using aqueous alkalis or ammonia in the presence of the surfactant or polymeric protective colloid. Nonetheless, Zhang *et al.* teach (claim 12) increasing the pH of the solution to precipitate out the final hydroxyapatite product (see page 25 Experimental procedures) with an ammonium. The salts desired to be precipitated would be chosen based on the desired product such that one of ordinary skill in the art

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would find it obvious to use various salts including phosphate salts if the final product contained phosphate.

One of ordinary skill in the art would have combined the teachings and as combined the references make obvious the above claims because both references are drawn to compositions with stomatological applications and particularly for application on teeth or bone. Further, Rudin *et al.* teach that the finely divided nanoparticulate hydroxyapatite particles possess a high adhesive-sorption activity which favor the preventative measures of the composition (see page 3 paragraphs 4-5). Rudin *et al.* thus motivates one skilled in the art to employ the hydroxyapatite/polyacrylic composition of Zhang *et al.* who show that the addition of polyacrylic acid can reduce the size of the hydroxyapatite particles (see page 26, Results and discussion section). Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 21 of copending Application No. 10/297,842 in view of PCT/IB97/01634 to Rudin *et al.* This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows

Claim 21 of the '842 application claims an oral care composition comprising a nanoparticulate hydroxide, carbonate or phosphate compound and a surface modifying agent. A surface modifying agent can be for example an amino acid like polyaspartic acid or pectins which are described in the instant specification on page 7 as protective colloids. Further it would be obvious to one skilled in the art to compose a toothpaste comprising the above ingredients as described in Rudin *et al.*



**Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

15 August 2005  
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